# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO.

Muriel McHugh and Michael McHugh, PLAINTIFFS	) ) )		
vs.	) ) )	PLAINTIFFS' AND JURY	COMPLAINT DEMAND
Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics, DEFENDANT	) ) )		

## COMPLAINT

NOW COME the plaintiffs, Muriel McHugh and Michael McHugh, by and through the undersigned counsel, and bring this Complaint against defendant, Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics.

1. This is an action for damages relating to defendant's development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the Defective Device sold under the name "Rejuvenate System" which includes the Rejuvenate Modular Neck and Stem components (hereinafter, "Rejuvenate System" or "Defective Device").

#### PARTIES, JURISDICTION, AND VENUE

- The plaintiffs, Muriel McHugh and Michael McHugh, (hereinafter, "plaintiffs") are residents of the Town of Somerset, Bristol County, Commonwealth of Massachusetts.
- 3. The defendant, Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics (hereinafter, "Howmedica/Stryker"),

is a corporation organized and existing under the laws of New Jersey, having its principal place of business located at 325 Corporate Drive, Mahway, New Jersey, and conducting business throughout the United States, including the Commonwealth of Massachusetts.

- 4. The Court has original jurisdiction under 28 U.S.C. § 1332 because this action is between citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of costs and interest. The plaintiffs are citizens and residents of the Commonwealth of Massachusetts. The defendant is a citizen and resident of the state of New Jersey.
- 5. Venue is proper in the United States District Court for the District of Massachusetts because the wrongful acts upon which this lawsuit is based occurred, in part, in this District and the plaintiffs reside in the Town of Somerset. Venue is proper pursuant to 28 U.S.C. § 1391(c) because the defendant is a corporation that has substantial, systematic, and continuous contacts in this District and is subject to personal jurisdiction in this District.
- 6. Further, venue is proper in the United States
  District Court for the District of Massachusetts because it
  is a judicial district in which a substantial part of the
  events or omissions giving rise to the claims making the basis
  of this lawsuit occurred.

#### THE PRODUCT

- 7. At all times material hereto, the defendant, Howmedica/
  Stryker (hereinafter collectively referred to as "defendant"
  or "Stryker"), developed, tested, assembled, manufactured,
  packaged, labeled, prepared, distributed, marketed, supplied,
  and/or sold the Defective Device either directly or indirectly
  to members of the general public within the Commonwealth of
  Massachusetts and elsewhere, including the plaintiff Muriel
  McHugh.
- 8. The defendant's Defective Device was placed into the stream of interstate commerce and was implanted in the plaintiff Muriel McHugh.
- 9. On or about January 12, 2011, the plaintiff Muriel McHugh underwent right-hip replacement at New England Baptist Hospital in Boston, Massachusetts, by Carl T. Talmo, M.D.
- 10. As a direct and proximate result of the defendant's placing the Defective Device into the stream of commerce, the plaintiff Muriel McHugh has suffered and continues to suffer both injuries and damages, including, but not limited to, past, present, and future physical and mental pain and suffering; past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; and other related damages.
- 11. On June 3, 2008, the defendant received FDA clearance to sell its Rejuvenate System in the United States.

- 12. Sometime during the first week of July, 2012, the defendant issued a voluntary worldwide recall of its Rejuvenate Hip Replacement System.
- 13. The Rejuvenate System is a dual modular hip replacement prosthesis. It is indicated for patients requiring primary total-hip arthroplasty or replacement due to painful joint disease of the hip resulting from non-inflammatory degenerative arthritis.
- 14. Unlike most prosthetic hip implants, the Rejuvenate System is an artificial hip-replacement device consisting of two basic components: a chrome cobalt neck that is inserted into a titanium stem. The Rejuvenate System can be used interchangeably with any number of Stryker-bearing surface components which comprise the ball and an acetabular cup or socket. The bearing surface system or components are unrelated to the Rejuvenate System's method of failure.
- 15. In its application for approval, the defendant maintained that the Defective Device was "intended to be used with any currently available compatible Howmedica Osteonics' acetabular components. Compatibility with the modular stems includes: V40 Biolox Delta, Biolox Delta Universal Taper Heads and Sleeves, V40 CoCr Heads, V40 LFIT CoCr Heads, C-Taper Alumina Heads when used with V40/C-taper Adaptor, C-Taper Delta Heads when used with C-taper Adaptor, UHR

Universal Head, and Unitrax Heads when used with Unitrax V40 Modular Adapter."

- 16. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc, and iron. Their alloy was designed and patented by the defendant and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants. In its promotional materials for the Rejuvenate System, the defendant claims that its alloy is both stronger and less rigid than other titanium alloys. It also claims that the particular titanium alloy has been tested and proven by the defendant to resist the effects of corrosion and fretting.
- 17. At all times material hereto, the Rejuvenate Modular Neck and Stem components implanted in the plaintiff Muriel McHugh were designed, manufactured, marketed, distributed, and/or supplied by the defendant.
- 18. After the implantation of the Defective Device, the plaintiff Muriel McHugh presented to Carl T. Talmo, MD, in Boston, Massachusetts, for examination in or about September, 2012, with complaints of pain and discomfort in the area of her Defective Device.
- 19. Diagnostic workup revealed the absence of device loosening, infection, malposition, or any other explanation for the plaintiff Muriel McHugh's symptoms.
  - 20. On or about May 1, 2013, based upon the plaintiff

Muriel McHugh's symptoms and diagnostic testing and examination, Dr. Carl T. Talmo recommended and scheduled revision surgery at New England Baptist Hospital due to the recall of the Defective Device.

- 21. During removal and replacement of the acetabular cup, Dr. Talmo confirmed the presence of pseudotumor and adverse tissue reaction that lead to failure of the device.
- 22. Subsequent to the revision surgery in May, 2013, the plaintiff Muriel McHugh dislocated her hip on June 22, 2013, and underwent a closed-reduction procedure on June 23, 2013.
- 23. While sitting in a recliner, the plaintiff Muriel McHugh again dislocated her hip on July 19, 2013, and underwent a right total-hip arthroplasty closed reduction on July 19, 2013.
- 24. Due to repetitive dislocations, the plaintiff Muriel McHugh underwent a right total-hip arthroplasty revision on August 8, 2013.

# THE STRYKER MODULAR HIP STEM HISTORY

25. In February, 2009, Stryker released its Rejuvenate Modular Primary Hip System, the latest evolution in the defendant's OmniFit and Secure-Fit Hip systems, which was approved for market by the FDA on June 3, 2008. The Rejuvenate Modular Hip is an extension of the Stryker Modular Hip, which was approved for market by the FDA on September 13, 2007.

- 26. According to Stryker's materials, the Rejuvenate Modular Primary Hip System was developed to optimize anatomic restoration by providing options that offer enhanced stability, proven modularity, and intra-operative flexibility. With a wide range of femoral stem and neck combinations and an extensive range of length, version, and offset, the Rejuvenate Modular Primary Hip System was marketed to enable surgeons to better personalize the implant to a patient's unique anatomy.
- 27. The Rejuvenate System is comprised of separate femoral stem and neck components and offers a variety of sizing options intra-operatively. The benefit, according to Stryker, was that by allowing the surgeon to independently manage leg length, neck version, and femoral offset, the system provides surgeons the ability to better personalize the biomechanics of a patient's hip replacement.
- 28. The Rejuvenate System combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fc) with a plasma-sprayed coating of commercially pure Ti and PureFix HA for the stem and CoCr for the neck. Stryker claims that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.
- 29. Despite Stryker's claims, this material combination has been reported to cause corrosion. Since the 1980s medical and scientific literature has reported corrosion to be a problem when Ti and CoCr have been used at modular junctions.

In its marketing and sale of the Defective Device, Stryker represented and warranted that its proprietary materials alleviate this problem.

30. The defendant holds two patents for modular implant devices. Currently, the defendant has a pending application to patent a modular hip prosthesis similar to the Rejuvenate System.

## URGENT SAFETY NOTICES AND RECALLS

- 31. In April, 2012, the defendant issued an Urgent Field Safety Notice (hereinafter, "Notice") to surgeons and hospitals in the United States regarding the Rejuvenate System.
- 32. In this Notice, the defendant acknowledged that it had received reports of device failure due to heavy metal contamination. The Notice specifically referred to failures at the taper neck junction between the neck and stem due to corrosion and fretting.
- 33. This corrosion and fretting was exactly the same failure mechanism that the defendant had warranted would not occur because of the Rejuvenate System's design and composition. It was also exactly the same failure mechanism that the medical and scientific community had been studying and documenting in modular device design since the 1980s.
- 34. The Notice went on to describe symptoms and findings identical to those experienced by the plaintiff Muriel McHugh.

- 35. Among those specifically mentioned in the Notice were tissue necrosis, metallosis, adverse soft-tissue reaction and pseudo-tumor formation.
- 36. Almost immediately following the Notice, the defendant issued a voluntary recall of the Stryker Rejuvenate

  System in Canada. In its recall notice, the defendant stated that it was amending the Instructions for Use for the device to include warnings that the defendant was on notice of the issues described in the Notice.
- 37. In the first week of July, 2012, the defendant issued a voluntary recall of all Stryker Rejuvenate Modular Hip Stems. As part of its recall notice, the defendant once again cited reports of device failure due to heavy metal corrosion and fretting.

### THE FEDERAL REQUIREMENTS

- 38. Federal regulation states: "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." See 21 CFR § 7.3(g).
- 39. Federal regulation states: "Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard

presented by the product being recalled." See 21 CFR § 7.3(m).

- 40. Federal regular states: "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR § 7.3(m).
- 41. The classification of the product withdrawals and corrections of the defendant's devices (described above) as Class II Recalls by the FDA confirms by definition that the devices were in violation of federal laws and that initiation of legal action or seizure would be indicated for these devices.
- 42. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with federal requirements. See. 21 U.S.C. § 351.
- 43. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. See 21 U.S.C. § 352.

- 44. Pursuant to federal law, manufacturers are required to comply with FDA regulations of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports of any medical device that may have caused or contributed to death or serious injury or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury.
- 45. Federal law also mandates that FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. § 360(i).
- 46. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within thirty (30) days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reason-ably known to the manufacturer, including any information that can be obtained by analysis, testing, or

other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event and must evaluate the cause of the adverse event. See 21 CFR § 803.50.

- 47. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual, adverse-event report whether remedial action was taken in regard to the adverse event and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR § 803.52.
- 48. Pursuant to federal regulation, manufacturers must report to FDA in five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR § 803.53.
- 49. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device or to remedy a violation of the ACI caused by the device which may present a risk to health. The written submission must contain, among other things, a description

of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. See 21 CFR § 806.

- 50. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design-control requirements, including, but not limited to, conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, investigate the cause of nonconforming products, and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR § 820.
  - 51. Pursuant to federal regulation, a manufacturer must

report to FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incident of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."

52. Specifically, it is believed that with respect to the Rejuvenate System, the defendant failed to timely report adverse events; failed to timely conduct failure investigations and analyses; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidents of adverse effects, or device failures necessitating a labeling, manufacturing, or device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

### CAUSES OF ACTION

# COUNT I - NEGLIGENCE

- 53. The plaintiffs reallege and incorporate by reference the allegations set forth above in paragraphs 1 through 52.
- 54. The defendant designed, manufactured, marketed, detailed, and advertised both to physicians and consumers the Rejuvenate System.

- 55. As a result, the defendant had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom the Defective Device would be implanted.
- 56. The defendant failed to use reasonable and due care for the safety and well-being of those in whom the Defective Device would be implanted and is, therefore, negligent in the following respects:
  - a) The defendant failed to adequately design and manufacture the Defective Device to insure that it would not corrode, erode, deteriorate, and induce severe metal toxicity in the patient. The flaws include, but are not limited to:
    - i. the incompatibility of the TMZF titanium with other Defective Device components;
    - ii. poor design of the taper neck junction
       between the stem and neck such that micro
       motion was predictable;
    - iii. poor manufacturing practices such that the taper neck junction between the neck and stem do not "fit" the way they were intended;
      - iv. a combination of the above factors leads to rapid and severe heavy metal castoff causing soft tissue and bony necrosis, pain, and premature failure of the Defective Device.
  - b) The defendant failed to adequately test the Defective Device to insure that it would not corrode, erode, deteriorate, and induce severe metal toxicity in the patient.
  - c) The defendant failed to conduct anything other than bench testing so that when manufactured and marketed, patients become, in essence, the defendant's first clinical trial.

- d) The defendant made affirmative representations that the Defective Device would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer.
- e) The defendant trained its sales force to detail the Defective Device utilizing representations that the defendant knew or should have known were false, creating in the minds of both surgeons and consumers that the Defective Device would not cause metal toxicity.
- f) The defendant specifically marketed the Defective Device as a safe alternative to metal-on-metal bearing surface devices that had been widely publicized as capable of causing premature failure due to heavy metal toxicity.
- g) The defendant marketed this Defective Device as a "perfect fit" for younger patients due to its modular deign, creating in the minds of physicians and consumers that the Defective Device was superior to other available hip implants when, in fact, the Defective Device was so poorly designed, constructed, and tested that it had to be recalled from the market only three years after it was introduced.
- h) The defendant failed to manufacture the product to the defendant's own internal specifications such that the taper neck junction between the neck and stem prematurely failed, causing metal debris castoff and severe metal toxicity in patients.
- i) The defendant failed to adequately test the TMZ alloy's compatibility with chrome cobalt components in an effort to prevent corrosion and fretting at the neck/stem taper neck junction of this modular Defective Device;
- j) The defendant failed to promptly act upon reports of early failure such that the Defective Device continued to be implanted in unknowing patients by surgeons well after it should have been recalled.
- k) The defendant chose as its predicate Defective Device a system that had known disastrous

- failures, had to be redesigned, and is the subject of protracted litigation.
- 1) The defendant was on actual notice prior to marketing the Rejuvenate System that its TMZF titanium alloy performed poorly when mated with its chrome cobalt components. The defendant knew when it introduced the Rejuvenate System to the market that the Stryker Accolade device, as well as other Stryker devices, were experiencing corrosion.
- 57. The above conduct exhibits the defendant's failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature Defective Device failure as well as severe, debilitating injuries that were permanent.
- 58. As a direct and proximate result of the defendant's negligence, the plaintiffs sustained severe physical pain and suffering, bodily injury, physical impairment, disfigurement, emotional distress, mental anguish, loss of capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages, and loss-of-earning capacity. These damages have occurred in the past and will continue into the future.

WHEREFORE, the plaintiff Muriel McHugh requests that she be granted relief against the defendant as contained in the Prayer for Relief.

## COUNT II - BREACH OF EXPRESS WARRANTY

59. The plaintiffs reallage and incorporate by reference the allegations set forth above in paragraphs 1 through 58.

- 60. Through their public statements, their descriptions of the Rejuvenate System, and their promises relating to the Rejuvenate System, the defendant expressly warranted among other things that the Rejuvenate System was efficacious and safe for its intended use; was designed and constructed of materials that would prevent fretting and corrosion; and would last longer than competing hip implant devices; and was more suitable for younger adults that other devices given its purported longevity.
- 61. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Rejuvenate System, but which contained material misrepresentations and utterly failed to warn of the risks of the Rejuvenate System; (iii) verbal assurances made by the defendant's consumer-relations personnel to the public about the safety of the Rejuvenate System and the down-playing of the risks associated with the Rejuvenate System; and (iv) false and misleading written information supplied by the defendant.
- 62. The most prominent representation made by the defendant was on its website where it expressly warranted that the design, testing, and materials utilized in the Rejuvenate System would prevent fretting and corrosion.

- 63. The plaintiffs further allege that all of the aforementioned written materials are known to the defendant and in its possession, and it is the plaintiffs' reasonable belief that these materials shall be produced by the defendant and be made of record once the plaintiffs are afforded the opportunity to conduct discovery.
- 64. When the defendant made these express warranties, the defendant knew the purpose for which the Rejuvenate System was to be used and warranted it to be in all respects safe and proper for such purpose.
- 65. The defendant drafted the documents and/or made the statements upon which these warranty claims are based and, in so doing, defined the terms of those warranties.
- 66. The Rejuvenate System does not conform to the defendant's representations in that it is not safe and produces serious side effects.
- 67. As such, the Rejuvenate System does not conform to the defendant's promises and descriptions or affirmations of fact and was not adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used.
- 68. The defendant, therefore, breached its express warranties to the plaintiffs in violation of Massachusetts statutory and common law by manufacturing, marketing, and selling the Rejuvenate System to the plaintiff Muriel McHugh, causing damages as will be established as trial.

WHEREFORE, the plaintiff Muriel McHugh respectfully requests that she be granted relief against the defendant as contained in the Prayer for Relief.

### COUNT III - BREACH OF IMPLIED WARRANTY

- 69. The plaintiff Muriel McHugh realleges and incorporates by reference the allegations set forth above in paragraphs 1 through 68.
- 70. Through its public statements, its descriptions of the Rejuvenate System, and its promises relating to the Rejuvenate System, the defendant impliedly warranted, among other things, that the Rejuvenate System was efficacious and safe for its intended use; was designed and constructed of materials that would prevent fretting and corrosion; would last longer than competing acetabular devices; and was more suitable for younger adults than other devices given its purported longevity.
- 71. These implied warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Rejuvenate System, but which contained material misrepresentations and utterly failed to warn of the risks of the Rejuvenate System; (iii) verbal assurances made by the defendant's consumer-relations personnel to the public about

the safety of the Rejuvenate System and the down-playing of the risks associated with the Rejuvenate System; and (iv) false and misleading written information supplied by the defendant.

- 72. The plaintiff further alleges that all of the aforementioned written materials are known to the defendant and in its possession, and it is the plaintiffs' reasonable belief that these materials shall be produced by the defendant and be made of record once the plaintiffs are afforded the opportunity to conduct discovery.
- 73. When the defendant made these implied warranties, the defendant knew the purpose for which the Rejuvenate System was to be used and impliedly warranted it to be in all respects safe and proper for such purpose.
- 74. The defendant drafted the documents and/or made the statements upon which these warranty claims are based and, in so doing, defined the terms of those warranties.
- 75. The Rejuvenate System does not conform to the defendant's representations in that it is not safe and produces serious side effects.
- 76. As such, the Rejuvenate System did not conform to the defendant's promises, descriptions, or affirmations of fact and was not adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used.

77. The defendant, therefore, breached its implied warranties to the plaintiff Muriel McHugh in violation of Massachusetts law by manufacturing, marketing, and selling the Rejuvenate System to the plaintiff Muriel McHugh; and, as a result, the plaintiffs sustained severe physical pain and suffering, bodily injury, physical impairment, disfigurement, emotional distress, mental anguish, loss of capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages, and loss-of-earning capacity. These damages have occurred in the past and will continue into the future.

WHEREFORE, the plaintiff Muriel McHugh respectfully requests that she be granted relief against the defendant as contained in the Prayer for Relief.

# COUNT IV - LOSS OF CONSORTIUM

- 78. The plaintiff Muriel McHugh realleges and incorporates by reference the allegations set forth above in paragraphs 1 through 77.
- 79. At all times material, the plaintiff Michael McHugh was married to the plaintiff Muriel McHugh.
- 80. As a result of the injuries and damages sustained by his spouse, Muriel McHugh, the plaintiff Michael McHugh has suffered the loss of his spouse's care, comfort, society, and affections.

WHEREFORE, the plaintiff Michael McHugh respectfully requests that he be granted relief against the defendant as contained in the Prayer for Relief.

## PRAYER FOR RELIEF

WHEREFORE, the plaintiffs pray for judgment against the defendant as follows:

- a) awarding compensatory damages in the amount of \$1,000,000.00 for resulting from the defendant's violation of Massachusetts law;
- b) awarding compensatory damages in the amount of \$1,000,000.00 for the defendant's breach of implied and express warranties, for the defendant's negligence, and for loss of consortium;
- c) awarding actual damages to the plaintiffs incidental to the plaintiffs' purchase and use of the Rejuvenate System in an amount to be determined at trial;
- d) awarding pre-judgment and post-judgment interest to the plaintiffs as provided by law;
- e) awarding reasonable attorney's fees and costs to the plaintiffs as provided by law; and
- f) granting all such other relief as the Court deems necessary, just, and proper.

THE PLAINTIFFS CLAIM A TRIAL BY JURY IN THE ABOVE-ENTITLED MATTER.

By their Attorneys,

FOLAN & McGLONE,

Ву:\_\_

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